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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/524,101 | 03/13/2000 | Andrew Roy Buchman | EX00-015 | 6972 |

23500 7590 11/28/2001

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| EXAMINER |
|---|
| TAYLOR, JANELL E |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1655 | |

DATE MAILED: 11/28/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/524,101 | Applicant(s) BUCHMAN ET AL. | |
|---|---|---|---|
| | Examiner Janell Taylor Cleveland | Art Unit 1655 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *14-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ *Notice of References Cited* (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ *Interview Summary* (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 14-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Claims 1-13 and SEQ ID NOS: 1 and 2 are hereby elected. Election was made **without** traverse in Paper No. 7.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 3 is drawn to the isolated nucleic acid molecule of claim 1 wherein the nucleic acid sequence has at least 50% identity with SEQ ID NO: 1. Claim 7 is drawn to an isolated nucleic acid molecule of claim 1 wherein the sequence encodes a polypeptide having at least 50% sequence identity with SEQ ID NO: 2. There is not adequate written description given in the specification to support the claim to a sequence having about 50% identity.

Applicant is referred to the revised interim guidelines on written description published December 21, 1999 in the Federal Register, Volume 64, Number 244, page 71427-71440 (also available at www.uspto.gov).

When the claims are analyzed in light of the specification, instant invention encompasses 50% or greater identity to the given nucleotide sequences. However, the specification discloses only the actual nucleotide sequences as represented by their SEQ ID NOS. In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, the actual sequences represented by the SEQ ID NOS are the only species whose complete structure is disclosed. The specification does not provide any disclosure as to what would have been the structure for 50% or greater homology.

This limited information is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of polynucleotides besides those given, i.e., degenerates thereof or fragments thereof, that are encoded by the sequences disclosed at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

A functional activity for the nucleic acid molecule itself is not set forth in the claims. Accordingly, the claims are inclusive of nucleic acid molecules which are allelic variants and which encode for proteins lacking the functional activity of p53. The specification has not identified any allelic variants and which encode for proteins lacking the functional activities of p53. The specification has not identified any allelic

variants of p53 having biological activities distinct from wild-type protein. The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles. The structure and function of one molecule does not provide guidance as to the structure and function of other molecules.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. In The Regents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "an adequate written description of DNA…'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed invention." The limited information provided in the specification is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of a full length genomic sequence encoding allelic variants of PHA synthase having any functional activity, or of the broad genus of nucleic acids having any level of sequence complementarity with SEQ ID NOS: 1 or 3. Therefore, the written description requirement has not been satisfied for the claims are they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent

Applications under 35 USC 112, 1st Paragraph "Written Description" Requirement,

Federal Register, Vol. 66, No. 4, pages 1099-1111.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites amino acid sequences and depends from claim 1, but since no specific SEQ ID NO is given, it is not clear if these amino acid sequences are part of the larger SEQ ID NO: 2, and if so, which portion. Applicant is required to specifically show where these sequences are found within a larger sequence or to provide SEQ ID NOS for the sequences. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

6. Claims 1, 5, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Harvey et al. (Genbank Accession Number AI516383).

Claim 1 is drawn to "an isolated nucleotide molecule comprising a nucleic acid sequence selected from the group consisting of: b) a nucleic acid sequence which encodes a polypeptide comprising at least 7 contiguous amino acids of the amino acid SEQ ID NO: 2; d) a nucleotide sequence that encodes a polypeptide comprising at least 9 contiguous amino acids that share 100% sequence identity to the nucleotide

sequence set forth in SEQ ID NO: 2; e) at least 20 contiguous nucleotides of any of nucleotides 1-111 of SEQ ID NO: 1; g) the complement of a-f. Claim 5 is drawn to the nucleic acid sequence encoding at least 17 contiguous amino acid sequences of SEQ ID NO: 2. Claim 6 is drawn to the nucleic acid sequence encoding at least 19 contiguous amino acid sequences of SEQ ID NO: 2.

Harvey et al. teach a nucleic acid sequence which encodes a Drosophilia melanogaster embryo pOT2 cDNA clone. Nucleic acid bases 1-650 of Harvey correspond to nucleic acid bases 67-716 of instant SEQ ID NO: 1. Although 2 base differences are found at the end of the sequence, Harvey still anticipates the claims because Harvey teaches at least 500 nucleic acid contiguous sequences which are identical to those of SEQ ID NO: 1, thereby fulfilling the requirement of claim 1, part e) which is drawn to at least 20 contiguous nucleotides, and to claims 5 and 6, which correspond to 51 and 57 nucleic acid bases. Harvey therefore fully anticipates the claims.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 2, 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harvey et al.

Claim 2 is drawn to the sequence being RNA. Claims 8-10 are drawn to the nucleic acid being from a p53 domain. Claim 11 is drawn to a vector. Claim 12 is drawn to a host cell. Claim 13 is drawn to a process for producing a p53 polypeptide comprising culturing the host cell of claim 8 under conditions suitable for expression of the 53 polypeptide and recovering the polypeptide.

As disclosed above, Harvey et al. teach a nucleic acid sequence which encodes a Drosophilia melanogaster embryo pOT2 cDNA clone. Nucleic acid bases 1-650 of Harvey correspond to nucleic acid bases 67-716 of instant SEQ ID NO: 1. Although 2 base differences are found at the end of the sequence, Harvey still anticipates the claims because Harvey teaches at least 500 nucleic acid contiguous sequences which are identical to those of SEQ ID NO: 1, thereby fulfilling the requirement of claim 1, part e) which is drawn to at least 20 contiguous nucleotides, and to claims 5 and 6, which correspond to 51 and 57 nucleic acid bases. Harvey therefore fully anticipates the claims.

Harvey et al. does not disclose RNA, or the p53 domain, or a vector or host cell, or producing a polypeptide.

It would have been obvious to one of ordinary skill in the art that the sequence may have been RNA. This is because it was well known in the art that RNA exists in the cell and is often the form in which a sequence is identified. It would have been obvious that the sequence is derived from a p53 domain. This is because the p53 domain was known to exist in animals, including the fruit fly. It would have been obvious that the sequence may have been used in a vector or a host cell, as these two components are

known to be useful in synthesizing a protein. It would have been obvious to produce the polypeptide of claim 1 by culturing a host cell as this was a well recognized way of synthesizing a protein.

***Summary***

Claims 3 and 7 are rejected under 35 U.S.C. 112, first paragraph. Claim 4 is rejected under 35 U.S.C. 112, second paragraph. Claims 1, 5, and 6 are rejected under 35 U.S.C. 102(b). Claims 2, 8-13 are rejected under 35 U.S.C. 103(a). Claims 3, 4, 7, are free of the prior art but are rejected for other reasons.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland, whose telephone number is (703) 305-0273.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Any inquiries of a general nature relating to this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1634 via the PTO Fax Center using (703) 305-3014 or 305-4227. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Janell Taylor Cleveland

November 19, 2001

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600